



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 29.05.2000

C(2000) 1410

NOT FOR PUBLICATION

COMMISSION DECISION

Of 29.05.2000

amending the marketing authorization for the
medicinal product for human use

"CETROTIDE - Cetrorelix (as acetate)"

Only the German text is authentic

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THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products,¹ as amended by Commission Regulation (EC) No 649/98,²

Having regard to Council Directive 92/27/EEC of 31 March 1992 on the labelling of medicinal products for human use and on package leaflets,³ and in particular Article 10(3) thereof,

Having regard to the request to change the package leaflet concerning the medicinal product **"CETROTIDE - Cetrorelix (as acetate)"** entered in the Community register of medicinal products under No: EU/1/99/100/001-002, submitted on 11 February 2000 pursuant to Article 10(3) of the abovementioned Council Directive,

Whereas:

- (1) the proposed changes are not connected with the contents of the summary of characteristics of the medicinal product in question;
- (2) the package leaflet as changed continue to comply with the requirements of Directive 92/27/EEC;
- (3) Decision C(1999) 939 of 13 April 1999 authorising the placing on the market of the medicinal product **"CETROTIDE - Cetrorelix (as acetate)"** should therefore be amended,

¹ OJ No L 214, 24. 8. 1993, p. 1.

² OJ No L 88, 24.3.1998, p. 7.

³ OJ L 113, 30.4.1992, p. 8.

HAS ADOPTED THIS DECISION:

Article 1

Decision C(1999) 939 is hereby amended as follows:

(a) Annex III B (package leaflet) is replaced by Annex I to this Decision.

Article 2

This Decision is addressed to ASTA Medica Aktiengesellschaft, An der Pikardie 10, 01227 Dresden, Deutschland.

Done at Brussels, 29.05.2000

For the Commission

Erkki LIIKANEN
Member of the Commission